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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,424	07/18/2000	Yoichi Taya	49979	9451
21874	7590	03/24/2004		
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER PADMANABHAN, KARTIC	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 03/24/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/618,424	Applicant(s) TAYA ET AL.	
	Examiner Kartic Padmanabhan	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lill et al. (Nature, 1997).

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Lill et al. teach that p300/CBP (which is considered to be an acetyltransferase) binds to p53 in the absence of viral oncoproteins. The reference also teaches that E1A disrupts binding of p300/CBP to p53 by binding to p300/CBP. The reference teaches the tagging of p53 with green fluorescent protein in a binding assay to show the binding of p300/CBP to p53. However, when E1A is cotransfected with GFP-P53 and epitope tagged p300, binding does not occur. The reference does not teach a kit, nor does it teach deacetylase.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to package the components of Lill et al. in a kit due to the long recognized ease and convenience conferred by such an arrangement. In addition, the various reagents used to carry out an assay are often packaged together in a kit, which a skilled artisan would have known. In addition, it would have been obvious to make deacetylase a component of the kit. Since the claimed method recites selecting a compound that is associated with an increase or decrease in the amount of acetylated peptide, one would have had a reasonable expectation of success in making deacetylase a component of the kit and using it to deacetylate acetylated peptide substrates.

5. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al. (Cell, 1997).

Gu et al. teach that p53 is a substrate for p300 acetyltransferase. P53 was labeled by acetyl CoA, but labeling required the presence of both acetyl CoA and p300. The reference also teaches that bacterially produced p53 is inactive in DNA binding, but binding can be activated by anti-p53 monoclonal antibody. Acetylation of p300 also dramatically increases the DNA-

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binding activity if fixed amounts of p53. The reference does not teach a screening assay or the use of biotin to label the peptide substrate.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to package the components of Lill et al. in a kit due to the long recognized ease and convenience conferred by such an arrangement. In addition, the various reagents used to carry out an assay are often packaged together in a kit, which a skilled artisan would have known. In addition, it would have been obvious to make deacetylase a component of the kit. Since the claimed method recites selecting a compound that is associated with an increase or decrease in the amount of acetylated peptide, one would have had a reasonable expectation of success in making deacetylase a component of the kit and using it to deacetylate acetylated peptide substrates.

Allowable Subject Matter

6. In view of applicant's amendments and arguments, claims 16-22 are allowed.
7. For detailed reasons for allowance, applicant is directed to the prior office action mailed on August 26, 2003 and labeled as Paper # 25.

Response to Arguments

8. Applicant's arguments filed 1/29/04 have been fully considered but they are not persuasive.
9. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge

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generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). The examiner maintains that such motivation exists in the knowledge generally available to one of ordinary skill in the art. To refute this position, applicant simply contends this not to be the case without any rationale for this position or basis in fact, which renders the position prima facie unconvincing. In addition, this argument essentially fails to comply with 37 CFR 1.111(b) because it amounts to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

10. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

11. In response to applicant's argument that the prior art fails to teach a screening method, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in

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a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

12. Although applicant has amended claims 23 and 24 to parallel the method claims, the kit claims still only require the actual components of the kit (which have not been amended), and the use of the kit (antibody recognizing a specific substrate) does not merit patentable weight in claims drawn to a kit (intended use – see previous paragraph).

Conclusion

Claims 16-22 are allowed, and claims 23-24 remain rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
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03/22/04